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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,461	03/02/2001	Esteban Cvitkovich	4512/80212	9636

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EXAMINER	
SPIVACK, PHYLLIS G	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,461	CVITKOVICH ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Amendment/Response filed March 23, 2006 is acknowledged. New claim 23 is presented. Claims 12-23 are now under consideration.

An amendment to the title is noted.

Applicants again choose to hold the obviousness-type double patenting rejection in abeyance. The rejection of record is maintained.

In the last Office Action claims 12-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Taamma et al., Eur. J. Cancer, in view of Barrera et al., Proceedings of the American Association for Cancer Research. It was asserted Taamma teaches cyclic intravenous administration of Et-743 in the treatment of various solid tumors, such as breast or ovarian cancer, for an infusion time of 24 hours every 3 weeks. The patient population included those who were designated "refractory" to standard chemotherapy, and thus these patients, as required by claim 20, had previously been treated for cancer with chemotherapy. As required by claims 21 and 22, Barrera teaches the co-administration of an additional drug with ET-743, such as doxorubicin docetaxel, cisplatin, navalbine or DTIC. Variations in infusion times and dosing intervals of ET-743 are taught in the prior art. Treatment of sarcoma with ET-743 is known in the prior art as well. A period of recovery between doses to be administered in cycles is conventional practice.

Applicants argue the amendment to claim 12, the limitation "wherein said treatment results in a reduction in tumor size or a reduction in the level of a tumor marker" drawn to a reduction in the level or the elimination of the tumor marker, as well as the disclosures in Figure 1 and Examples 1-3, serve as indications of a reduction in

tumor size or growth. Applicants note most of the patients in Figure 1 and Examples 1-3 had received at least one prior course of unsuccessful treatment with another anti-tumor agent.

Applicants urge – other than an acknowledgement that ET-743 is in phase I clinical trials – a clinical response is not observed in human patients. The statement "Dose-escalation continues, currently nearing the expected pharmacoactive range level" indicates a clinical response has not been reached.

Applicants' arguments have been given careful consideration but are not found persuasive. The rejection of record under 35 U.S.C. 103 is maintained and currently extended to new claim 23. See the Tables on page 930 in Goodman & Gilman where dexamethasone is shown to be effective as an antiemetic in cancer chemotherapeutic regimens.

Taamma teaches administration of ET-743 to human patients in Phase I clinical trials. Barrera states ET-743 is entering Phase II Clinical Trials. A reduction of a tumor marker, such as CA-125, is well established in the prior art as indicative of chemotherapeutic efficacy. In this respect it is noted Applicants' disclosure is drawn solely to an ovarian tumor cell line.

While the prior art does not disclose clear clinical outcomes aligned with tumor types, the teachings of Taamma and Barrera provide ample motivation to administer ET-743, optionally in combination with an additional drug, to treat a human patient for cancer with a reasonable expectation of success.

The recitation in Taamma "Dose-escalation continues, currently nearing the expected pharmacoactive range level" more probably refers to the pharmacokinetic profile of ET-743 and the observed dose-limiting toxicity – myelosuppression – that restricts administration of ET-743 in its therapeutic range.

One skilled in the oncology art in view of the teachings of the prior art of record in the present application, would have been motivated to seek an optimal dosing regimen with respect to infusion times and intervals of administration through no more than routine experimentation.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

May 31, 2006,

Phyllis Spivack
PHYLLIS SPIVACK
PRIMARY EXAMINER
1614